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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,660	04/15/2005	Luis Molina	11299.105005	3876

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KING & SPALDING LLP
1180 PEACHTREE STREET
ATLANTA, GA 30309-3521

EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,660	MOLINA, LUIS	
	Examiner	Art Unit	
	MARCELA M. CORDERO GARCIA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the reply received on 30 July 2008.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Status of the claims

Claims 1-11 are pending in the application. Claims 1-11 are presented for examination on the merits.

REJECTIONS MAINTANED

Claim Rejections - 35 USC § 103

Applicant's arguments

Applicants respectfully disagree with the Examiner's reading of the references Blackburn and Thomas. Thomas does not teach a method of treating blepharitis comprising administering a therapeutically effective amount of a "broad range antibiotic" composition. Thomas teaches a method of treating sequealae of degenerative eye disease, such as inflammation, using a histidine composition (column 3, lines 40-43; column 4, lines 55-67) to decrease inflammation. In certain embodiments, antibiotics are coadminstered, but these are not taught as being useful for treatment of any dry eye diseases. Contrary to the Examiner's assertion, Thomas does not teach or suggest the use of a broad range antibiotic composition for treating blepharitis. Indeed, Thomas directs one of skill in the art away from the use of any antibiotics to treat dry eye diseases, stating that many antibiotics are not well-tolerated, give rise to toxicities, or are of only moderate efficacy (column 3, lines 12-14). Therefore one of ordinary skill in

the art would not be motivated to use any antibiotics, and in particular the claimed lanbiotics for treating blepharitis based on the teaching of Thomas.

Blackburn does not remedy the deficiencies of Thomas. Blackburn describes a composition comprising lysostaphin and a lanthionine contating bacteriocin for use as an antibiotic composition. Blackburn does not teach a method of treating dry eye disease using lanbiotics. As evidenced by Thomas, the use of antibiotics in treatment of ocular diseases was recognized as unpredictable (see column 3, lines 12-14). Therefore, absent some showing to the contrary by Blackburn, one of skill in the art would not have a reasonable expectation of successfully using a composition such as described in Blackburn to treat any ocular condition, more specifically dry eye disease. Without an expectation of success in the combination, one of ordinary skill in the art would not be motivated to substitute the histidine compositions as described in Thomas with the composition as taught by Blackburn, in order to derive the presently claimed invention.

Response to Arguments

Applicant's arguments filed 6/30/08 have been fully considered but they are not persuasive. Contrary to Applicant's assertions, Thomas does teach treating ocular inflammations and blepharitis [inflammation of the eyelids] with histidine and antibiotics which are active agents (e.g., column 5, lines 27; column 7, lines 52-64). Antibiotics such as broad spectrum penicillin are taught to be active agents in the treatment of the diseases (such as blepharitis and ocular inflammations in general). Further, Applicant's statement regarding that "Thomas directs one of skill in the art away from the use of any

antibiotics to treat dry eye diseases" has been considered but is not persuasive because column 3, lines 12-14 states that "Many antibiotics (e.g., beta-lactams and certain fluoroquinolones) are not well tolerated, give rise to toxicities, or are of moderate efficacy." For the reasons stated in column 3, lines 2-14, one skilled in the art would actually be motivated to look away from antibiotics such as beta-lactams and fluoroquinolones (which have undesired characteristics), and therefore the novel compositions of Blackburn with enhanced broad range bactericides (including duramycin, a lantibiotic) and activity against *S. aureus* (e.g., claims 2 and 19) would have been a desirable option in the treatment of microbial infections such as blepharitis, especially because it had broad range antibiotic properties (e.g., column 7, lines 60-64 of Thomas), activity against *S. aureus* (e.g., column 5, lines 15-22 of Thomas) and did not belong to the category of beta-lactams or fluoroquinolones which had toxicity, tolerance and efficacy problems.

Moreover, it has been held that under KSR that "obvious to try" may be an appropriate test under 103 The Supreme Court stated in KSR:

> When there is motivation "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, ___, 82 USPQ2d 1385, 1397 (2007).

The "problem" facing those in the art was the treatment of blepharitis [eyelid inflammation], and there were a limited number of methodologies available to do so. The skilled artisan would have had reason to try these methodologies with the

reasonable expectation that at least one would be successful. In the instant case the treatment encompassed histidine in combination with broad range antibiotics. Thus, selecting a broad range antibiotic such as duramycin to treat eyelid inflammation is a "the product not of innovation but of ordinary skill and common sense," leading to the conclusion that invention is not patentable as it would have been obvious. In addition, KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness.

See the recent Board decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Patt. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2s at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

REJECTION MAINTAINED

Double Patenting

Applicant's arguments

Because the obviousness-type double patenting rejection over 11/123,436 is provisional, Applicants request that the rejections be held in abeyance pending the determination of patentable subject matter.

Response to arguments

The ODP rejection of record is maintained for the reasons of record and because there has not been a terminal disclaimer provided by Applicant.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Marcela M Cordero Garcia/
Patent Examiner, Art Unit 1654

MMCG 09/08